

Appl. No. 10/009,083
Atty. Docket No. AA399XM
Amdt. dated 10/21/04
Reply to OA of 9/9/04
Customer No. 27752

REMARKS

Claim Status

Claims 1-37 are pending in the present application. No additional claims fee is believed to be due.

APPLICANTS' ELECTION WITH TRAVERSE

Claims 1-37 are pending in the present application. The present Office Action states that the claims are directed to more than one species of the generic invention. The Office Action states that the species are deemed to lack unity of invention because they are not so linked as to form a single general invention concept under PCT Rule 13.1. The Office Actions states the species are as follows: Claim 1 is drawn to an absorbent article comprising a body contacting surface and an absorbent core, wherein (1) at least a portion of the body contacting surface and (2) the skin care composition having a specific viscosity. The Office Action states that Claim 30 additionally contains the skin care composition comprising a skin care active ingredient.

With the choices given in the present Office Action, the Applicants elect Claim 1 with traverse.

In a reply on January 15, 2004, the Applicants have previously elected Claim 1 with traverse, so as to be in compliance with the M.P.E.P. The Examiner responded in an Office Action of April 29, 2004 by stating that the Applicants were non-responsive as to the election/restriction. The April 29th Office Action also stated that the Applicant must elect a single species which should include all the components of the composition as claimed. The April 29th Office Action further stated that this is an election of species and not a group restriction, see MPEP 8.023.

On May 10, 2004, the Attorney for the Applicants spoke to both Examiner Sabiha Qazi and the Examiner's supervisor Thurman Page on this matter. Two points were respectfully submitted and argued over the phone. First, the Office Action was very hard to comprehend, if not impossible to answer, due to the fact the Office Action cited a MPEP section that did not exist. Second, if one were to assume that the Examiner wished

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for the Applicants to choose a single composition from all the components, this type of election is inappropriate. For the subject matter of a lotion composition, it is common practice to recite lotion compositions as being semisolid under a specified temperature and in terms of parameters, such as, viscosity and shear stress. Moreover, because this is a very common practice to draft a claim in this way, it does not burden the Examiner in searching the art. Thus, the Examiner could file a substantive Office Action on the merits of this case without further election of lotion components. Both the Examiner and her supervisor agreed that the Examiner would file a substantive Office Action on the merits, rendering this action moot.

In the present September 9, 2004 Office Action, the Examiner has maintained the restriction requirement and the election of species. The Examiner has made conclusory statements that it is a burden on the Examiner to search the art and it is common practice for the Applicants to elect species. The Examiner has not given any rationale to explain the alleged burden on the Examiner to search. Moreover, the Examiner stated that the previous election of Claim 1 is incorrect and Claim 1 cannot be an elected species.

Applicants respectfully traverse this election requirement on multiple grounds.

First, the Applicants respectfully submit that the Examiner still has not satisfied various requirements in the M.P.E.P. in rendering the election of species requirement. M.P.E.P. §809.02 (a) provides that:

Where generic claims are present, the examiner should send a letter including only a restriction requirement or place a telephone requirement to restrict (the latter being encouraged). See MPEP § 812.01 for telephone practice in restriction requirements.

Action as follows should be taken:

(A) Identify generic claims or indicate that no generic claims are present. See MPEP § 806.04(d)(d) for definition of a generic claim.

(B) Clearly identify each (or in aggravated cases at least exemplary ones) of the disclosed species, to which claims are restricted. The species are preferably identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, respectively. In the absence of distinct figures or examples to identify the several species, the mechanical means, the particular material, or other distinguishing characteristic of the species should be stated for each species identified. If the species cannot be conveniently identified, the claims may be grouped in accordance with the species to which they are restricted.

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(C) Applicant should then be required to elect a single disclosed species under 35 U.S.C. 121, and advised as to the requisites of a complete reply and his or her rights under 37 CFR 1.141.

For generic claims, a search should not be made and art should not be cited.

Aside from the very brief statement that Claims 1 and 30 are generic claims and instructions that the Applicants must elect a species, the Examiner has failed to provide a requisite basis for the election of species requirement per Part (B) of M.P.E.P. §809.02 (a). The Examiner has not clearly identified the species to which claims are restricted. **In fact, no species has been identified by the Examiner.** The Examiner has not pointed to examples to identify the several species, the mechanical means, the particular material, or other distinguishing characteristic of the species which should be stated for each species identified as mandated by the M.P.E.P. in §809.02 (a)(B). Instead, the Examiner's comments regarding the election of species are conclusory statements that are blatant copies of sections of the M.P.E.P. that instruct the Applicant to elect. The Examiner's failure to provide the proper basis for the election of species requirement, further requirements of the M.P.E.P., makes it impossible for Applicant to elect a species and provide a meaningful traversal in this response.

Substantively, Applicants respectfully submit that each of the "species" of absorbent articles depicted in Claims 1-37 are related, in so far as they describe an absorbent article that comprises a body contacting surface and an absorbent core wherein at least a portion of the body contacting surface comprises an effective amount of a skin care composition which is solid or semisolid at 40°C and which is transferable from the body contacting surface to the wearer's skin by contact, normal wearer motion and body heat at a level effective in providing a skin benefit to the wearer's skin and the skin care composition has a viscosity of more than about 10^5 Poise under shear stress of less than about 3×10^4 dynes/cm², and viscosity of less than about 10^2 Poise under shear stress of less than about 3×10^6 dynes/cm² at 40°C. Claim 30 adds the limitation of the skin care composition comprises a skin care active ingredient.

Another requirement the Examiner has not satisfied in rendering the election of species requirement, is M.P.E.P. §808. M.P.E.P. §808 provides that:

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Every requirement to restrict has two aspects, (1) the reasons (as distinguished from the mere statement of conclusion) why the inventions as claimed are either independent or distinct, and (2) the reasons for insisting upon restriction therebetween as set forth in the following sections. (Emphasis in original)

M.P.E.P. §808.02 states that the Examiner, in order to establish reasons for insisting upon restriction, must share by appropriate explanation one of the following criteria: (1) separate classification thereof; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. The Examiner has pointed to none of these reasons for insisting upon restriction. M.P.E.P. §808.02, last paragraph, states that where, however, the classification is the same and the field of search is the same and there is no clear indication of separate feature classification in the field of search, no reasons exist for dividing among related inventions. This is presently the case in the present invention. The Examiner has provided no clear indication that the various claims would be put into separate future classifications or requires a different field of search. In fact, it is believed by the Applicants that the classification of the various alternative embodiments in the claims would be the same and the field of search is the same. For this reason alone the restriction requirement is improper.

Another requirement the Examiner has not satisfied in rendering the election of species requirement, is M.P.E.P. §806.01. M.P.E.P. §806.01 states that in passing upon questions of restriction, it is the "claimed subject matter" that is considered and such claimed subject matter "must be compared in order to determine the question of distinctiveness or independence." The Examiner has failed to make any consideration or comparison of the claimed subject matter in order to determine the question of distinctiveness or independence. The Examiner has merely provided conclusory statements that the application contains claims to patentably distinct species. There is no detailed analysis or comparison of any of the claims. This type of conclusory restriction requirement is improper under the rules.

Second, Applicants respectfully submit that the Examiner should be estopped from enforcing the restriction requirement due to the issuance of a substantive Office Action. The Examiner cannot argue that a search for prior art on the generic claims and

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species claims is unduly burdensome because the Examiner has completed a search for the prior art for the "generic" Claims 1 and 30. As well, the Examiner has submitted arguments on the prior art that was found in that search. Thus, the Applicants should not have to elect a species and the Examiner should be estopped from requiring a restriction of the Claims.

Third, due to the lack of clarity of election/restriction requirement, the Applicants maintain the traversal of the election between Claim 1 and Claim 30. As stated previously in the January 15, 2004 reply, if the election would be between the species in Claim 1 and Claim 30, the Applicants respectfully submit that the election is improper because Claim 1 and Claim 30 are clearly unpatentable over each other and belong to a single general invention concept. M.P.E.P. §808 provides **the election of species should not be required if the species claimed are considered clearly unpatentable over each other** (Emphasis in the original). Claim 1 recites an absorbent article comprising a body contacting surface and an absorbent core wherein at least a portion of the body contacting surface comprises an effective amount of a skin care composition which is solid or semisolid at 40°C and which is transferable from the body containing surface to the wearer's skin by contact, normal wearer motion and body heat at a level effective in providing a skin benefit to the wearer's skin and the skin care composition has a viscosity of more than about 10^5 Poise under shear stress of less than about 3×10^4 dynes/cm², and viscosity of less than about 10^2 Poise under shear stress of less than about 3×10^6 dynes/cm² at 40°C. Claim 30 recites an absorbent article comprising a body contacting surface and an absorbent core wherein at least a portion of the body contacting surface comprises an effective amount of a skin care composition which is solid or semisolid at 40°C and which is transferable from the body containing surface to the wearer's skin by contact, normal wearer motion and body heat at a level effective in providing a skin benefit to the wearer's skin, the skin care composition comprises a skin care active ingredient, and the skin care composition has a viscosity of more than about 10^5 Poise under shear stress of less than about 3×10^4 dynes/cm², and viscosity of less than about 10^2 Poise under shear stress of less than about 3×10^6 dynes/cm² at 40°C. Claim 30 merely adds the limitation of the skin care composition comprises a skin care active ingredient. Clearly, if the species contained in Claim 30 were allowed one could not practice the species contained

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in Claim 30 without infringing Claim 1. Thus, the restriction of the species in Claim 1 and Claim 30 is not proper because Claim 1 and Claim 30 are clearly unpatentable over each other. Moreover, Claim 1 and Claim 30 belong to a single inventive concept.

For all of the above reasons, Applicants hereby traverse the restriction requirement since the restriction in this instance is improper and the Examiner failed to provide the proper analysis and detailed explanation in the Restriction Requirement mandated by the rules. Further, the conclusory statements of the Examiner make it impossible for Applicant to provide a meaningful traversal. For all of the above reasons, the Restriction Requirement is improper and should be withdrawn.

Without clear indication of the species that the Applicants must elect, the Applicants have elected, with traverse, to prosecute the species in Claim 1. The claims that read on the elected species are Claims 1-29. Because the Examiner has not satisfied the burden of demonstrating that election between the species is proper, Applicants request reconsideration of the election of species requirement.

Rejection Under 35 USC §102 Over Gatto, et al.

Claims 1-37 are rejected under 35 U.S.C. § 102(e) as being anticipated by Gatto (U.S. Patent No. 6,570,054).

Applicants respectfully traverse the rejection.

The Office Action states that Gatto, et al. teaches and absorbent article having a stable skin care composition disposed on its skin-contacting surface. The Office Action further states that the applied reference has a common assignee with the instant application and based upon the earlier effective reference, it constitutes prior art under 35 U.S.C. § 102(e).

Claim 1 of the present invention recites an absorbent article that comprises a body contacting surface and an absorbent core, wherein at least a portion of the body contacting surface comprises an effective amount of a skin care composition which is solid or semisolid at 40°C. Claim 1 recites that the skin care composition is transferable from the body contacting surface to the wearer's skin by contact, normal wearer motion

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and body heat at a level effective in providing a skin benefit to the wearer's skin. Claim 1 recites that the skin care composition has viscosity of more than about 10^5 Poise under shear stress of less than about 3×10^4 dynes/cm², and viscosity of less than about 10^2 Poise under shear stress of more than about 10^6 dynes/cm², at 40°C. Claim 30 adds the limitation of the skin care composition comprises a skin care active ingredient.

Gatto does not teach each and every element in Claims 1 and 30. For, example, Gatto discloses an article having a skin care composition comprising a melt temperature of at least about 35°C and a solid of semi-solid consistency at about 20°C. Gatto does not teach or disclose a skin care composition that is solid or semisolid at 40°C because its' melt temperature is 35°C. Therefore, Gatto cannot anticipate the Applicants' Claims 1 and 30. Claims 2-29 depends from 1. Claim 31-37 depend from Claim 30. Therefore, Gatto does not render Claims 1-37 of the Applicants' present invention unpatentable under 35 U.S.C. § 102 (e).

Rejection Under 35 U.S.C. § 103 (a) Over Osborn, et al. (WO 98/55158), Van Rijswijk, et al. (WO 99/12530) and Roe, et al. (WO 99/22684).

Claims 1-37 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Osborn, et al. (WO 98/55158), Van Rijswijk, et al. (WO 99/12530) and Roe, et al. (WO 99/22684).

The Applicants respectfully traverse the rejection.

The Office Action states that Osborn, et al. teaches an absorbent article device that is pretreated with an emollient composition. The Office Action states that Van Rijswijk, et al teaches a skin care composition that provides a therapeutic and or protective skin care benefit upon transfer to the skin by a device. The Office Action states that Roe, et al. teaches a skin care composition to maintain and or improve skin health of the wearer upon transfer during use. It also teaches semisolid compositions. The Office Action states that the instant claims differ from the prior art in claiming a broader scope. The Office Action states that it would have been obvious to one skilled in the prior art at the time of the invention to prepare an absorbent article comprising a body containing surface and an absorbent core containing a skin care composition because the prior art teaches it.

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The Office Action states there is motivation to prepare the presently claimed invention by selecting the ingredients taught by the prior art *supra* for the same use. The Office Action states in absence of any criticality and/or unexpected results, the presently claimed invention is *prima facie* obvious over the prior art.

Claim 1 of the present invention recites an absorbent article that comprises a body contacting surface and an absorbent core, wherein at least a portion of the body contacting surface comprises an effective amount of a skin care composition which is solid or semisolid at 40°C. Claim 1 recites that the skin care composition is transferable from the body contacting surface to the wearer's skin by contact, normal wearer motion and body heat at a level effective in providing a skin benefit to the wearer's skin. Claim 1 recites that the skin care composition has viscosity of more than about 10^5 Poise under shear stress of less than about 3×10^4 dynes/cm², and viscosity of less than about 10^2 Poise under shear stress of more than about 10^6 dynes/cm², at 40°C. Claim 30 adds the limitation of the skin care composition comprises a skin care active ingredient.

Applicants respectfully submit that if one looks to the Applicants' invention and the references as a whole, Osborn, et al., Van Rijswijck, et al. and Roe, et al. separately or in combination do not render the Applicants' invention obvious. Osborn, et al., Van Rijswijck, et al. and Roe, et al. in combination or separately do not establish a *prima facie* case of obviousness because the references do not teach or suggest all of the claim limitations of Claims 1 and 30. Therefore, the claimed invention is unobvious and that the rejection should be withdrawn.

Applicants are unclear as to whether the Examiner is arguing the references separately or in combination; therefore the Applicants will address both possibilities. Osborn, et al., Van Rijswijck, et al. and Roe, et al. separately or in combination do not establish a *prima facie* case of obviousness because it does not teach or suggest all of the claim limitations of Claims 1 and 30. For example, Osborn, et al., discloses an absorbent interlabial device comprising a polysiloxane emollient composition that has a plastic or fluid consistency at 20°C. Likewise, Van Rijswijck, et al. and Roe, et al. discloses an article having a skin care composition comprising a final melt temperature where the skin care composition is 100% liquid of 45°C and a solid of semi-solid consistency at about 20°C. Osborn, et al., Van Rijswijck, et al. and Roe, et al. in combination or separately do

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not teach or disclose a skin care composition that is solid or semisolid at 40°C. Thus, the Osborn, et al., Van Rijswijck, et al. and Roe, et al. have not established a *prima facie* case of obviousness.

It is clear from the specification, that in the present application the Applicants chose different parameters for the skin care composition, so as to meet needs previously unsatisfied by the prior art. First, the Applicants were aware of the prior art references, Osborn, et al. Van Rijswijck, et al. and Roe, et al. and acknowledge these references with the specification on page 21, lines 15 to page 22, lines 13. Second, with the knowledge of the prior art, the Applicants also recognized a need for an absorbent article having a body contacting surface with a skin care composition disposed thereon that: (1) provides skin benefits; and (2) is as stable as possible before use of the absorbent article while transferable to the wearer's skin once the absorbent article is applied to the wearer's body. Third, the specification makes it that the temperature at which the skin care composition is semisolid and solid and the viscosity are critical in providing the unmet needs discussed above. The Applicants discuss the criticality of the temperature at which the skin care composition is semisolid and solid on page 22, lines 27-34 to page 23, lines 23. The specification states that the skin care compositions are solid or semisolid at 20°C and are solid or semisolid at 40°C. The specification states that this property ensures the stability of the skin care composition under static conditions such as conditions where the product is in storage and/or transport and maximizes the availability of the skin care composition being transferred to the skin for the skin effects under mechanical shear, such as, under conditions where the product is worn by the wearer and shear stress is applied to the skin care composition. The Applicants discuss the criticality of the viscosity ranges on page 23, lines 25-35 to page 24, lines 1-2. The specification states that when the skin care composition has a viscosity of less than about 10^2 Poise under shear stress of more than about 10^6 dynes/cm² at 40°C, the skin care composition has more tendency to transfer to the wearer's skin. Thus, the skin care composition tends to remain stable on the body contacting surface of the article in storage or transport, thereby requiring less initial amount of skin care composition disposed on the body contacting surface. Once the absorbent article is worn by the wearer, the skin care composition is exposed to higher shear stress than the shear stress in storage or transportation. Thereby, the skin care

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composition starts to flow and an effective amount of the skin care composition is transferred to the wearer's skin. Thus, the specification makes it clear that the Applicants chose different parameters for the skin care composition to get results that meet needs previously unsatisfied by the prior art.

Thus, Osborn, et al., Van Rijswijk, et al. and Roe, et al. in the combination or separately do not teach does not render the Applicants' Claims 1 and 30 obvious. Claims 2-29 depend from Claim 1. Claims 31-37 depend from Claim 30. Accordingly, Osborn, et al., Van Rijswijk, et al. and Roe, et al. in combination or separately do not teach does not render the Applicants' Claims 1-37 unpatentable under 35 U.S.C. § 103 (a).

Conclusion

In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 U.S.C. § 102 (b) and U.S.C. § 103. Applicants have made an earnest effort to distinguish the invention as now claimed from the applied references. In view of the foregoing, Applicants respectfully request reconsideration of this application, entry of the amendments presented herein, and allowance of Claims 1-37. Early and favorable action in the case is respectfully requested.

Respectfully submitted,

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